K062719

DEC - 1 2006

510(k) Summary Statement
For the GreenLight HPS™ Surgical Laser System & Accessories

General Information

A. Trade Name
GreenLight HPS™ Series Surgical Laser System & Accessories

B. Common Name
Laser Instrument, Surgical, Powered

C. Establishment Registration Number

2937094

D. Manufacturer's Identification

Laserscope
3070 Orchard Drive
San Jose, CA 95134-2011
(800) 243-9384-ext. 6795
(408) 943-9630 FAX

Official Correspondent
Paul Hardiman
Director, Regulatory Affairs

E. Device Classification

The GreenLight HPS™ Series Surgical Laser System & Accessories has been specifically classified as a Class II medical device by the OB/GYN, General Plastic Surgery, and ENT Device Advisory Panels.

F. Performance Standards

The GreenLight HPS™ Series Surgical Laser System & Accessories conforms with: Federal Regulations; the performance standards 21 CFR 1040.10 and 1040.11 for medical laser systems; and, International Harmonized Standards.

G. Predicate Devices:

- Laserscope Lyra Surgical Laser System & Accessories
- Laserscope Lyra G™ Surgical Laser System & Accessories
- 800 Series Surgical Laser System

K062719

- 800 Series Surgical Laser System & Accessories
- Modified Coherent VersaPulse Select Single Wavelength (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers and Delivery Devices with Accessories
- Laserscope Microbeam IV Micromanipulator

H. Product Description:

The Laserscope Gemini™ Surgical Laser System and Accessories consists of four major subsystems:

- The Optical and Laser resonator System
- The Electronics and Electrical System
- Operator Interface
- A variety of Delivery Devices and Accessories
- A Cooling Sub-system

I. Indications For Use:

The GreenLight HPS™ Surgical Laser System and Accessories is intended for the surgical incision/excision, vaporization, ablation and coagulation of soft tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands.

532nm Applications

General Surgery: Vaporizing, Coagulating, Incising, Excising, Debulking, and Ablating of Soft tissue as well as in minimally invasive Endoscopic (e.g. laparoscopic) or open surgeries.

Gastroenterology: Tissue ablation and hemostasis in the gastrointestinal tract; Esophageal neoplastic obstructions, including squamous cell carcinoma and adenocarcinoma; Gastrointestinal hemostasis (including Varices, Espohagitis, Esophageal Ulcer, Mallory-Weiss tear, Gastric Ulcer, Angiodysplasia, Stomal Ulcers, Non-bleeding Ulcers, Gastric erosions); Gastrointestinal Tissue ablation (Benign and Malignant neoplasm, Angiodysplasia, Polyps, Ulcer, Colitis, Hemorrhoids).

Gynecology: Vaporizing, incising, or coagulating tissue associated with treatments of conditions such as: Endometriosis; Cervical, vulvar, and vaginal intraepitheal neoplasia; Condyloma Acuminata; Uterine Septum; Intrauterine adhesions; Submucosal fibroids.

K062719

Head and Neck/Otorhinolaryngology (ENT): Tissue incision, excision, ablation, and vessel hemostasis.

Neurosurgery: Incising, excising, coagulating, and vaporizing neurological tumors of the firm textured type.

Opthamology: Post-vitrectomy endophotocoagulation of the retina.

Plastic Surgery: Vaporizing, Coagulating, Incising, Excising, debulking, and ablating of soft tissue in endoscopic and open procedures.

Spinal Surgery: Percutaneous lumbar diskectomy.

Thoracic Surgery: Vaporizing, Coagulating, Incising, Excising, Debulking, and ablating of soft tissue, including lung tissue in thoroscopic or open procedures.

Urology: Cutting, coagulating, or vaporizing urologic soft tissues. Open endoscopic minimally invasive urological surgery (ablation, vaporization, incision, excision and coagulation of soft tissue) including treatment of: Bladder; Urethral & Ureteral Tumors; Condylomas; Lesions of external genitalia; Urethral & penile Hemangioma; Urethral Strictures; Bladder Neck Obstructions; and, when used at 532nm it is intended to hemostatically vaporize prostate tissue of men suffering from benign prostate hyperplasia/hypoplasia (BPH). The device is not intended to treat prostate cancer.

1064nm Applications

Endoscopic/Laparoscopic General Surgery: Cutting, ablation, and/or hemostasis of soft tissue in endoscopic or laparoscopic general surgery applications, including but not limited to: Cholecystectomy, Appendectomy, Vagotomy, Pyloromyotomy.

Gastroenterology: Tissue ablation and hemostasis in the gastrointestinal tract; Esophageal neoplastic obstructions including Squamous cell carcinoma and Adenocarcinoma; Gastrointestinal hemostasis including: Varices, Espohagitis, Esophageal Ulcer, Mallory-Weiss tear, Gastric Ulcer, Angiodysplasia, Stomal ulcers, non-bleeding ulcers, Gastric erosions; Gastrointestinal tissue ablation including: Benign and malignant neoplasm; Angiodysplasia; Polyps; Ulcer; Colitis; Hemorrhoids.

K062719

General Surgery: Soft tissue general surgery applications: Skin incision; Tissue dissection; Excision of external tumors and lesions; complete or partial resection of internal organs, tumors, lesions; Tissue ablation; Vessel Coagulation.

Gynecology: Treatment of menorrhagia by photocoagulation of the endometrial lining of the uterus; Ablation of endometrial implants and/or peritoneal adhesions; Soft tissue excisional procedures, such as excisional conization of the cervix; intra-uterine gynecologic procedures where cutting, ablation and/or vessel coagulation may be indicated including Submucous fibroids, Benign endometrial polyps, Uterine septum.

Head and Neck/Otorhinolaryngology (ENT): Tissue incision, excision, ablation, and vessel hemostasis.

Hemostasis during Surgery: Adjunctive coagulation and hemostasis (bleeding control) during surgery in endoscopic (e.g. laparoscopic) and open procedures.

Neurosurgery: Hemostasis for: Pituitary Tumor; Meningioma; Hemagioblastoma; AVMs; Glioma; Glioblastoma; Astrocytoma; Oligodendroglioma.

Oculoplastics: Incision, Excision, Vaporization and/or coagulation of tissues in Oculoplastic procedures such as: Operations on the lacrimal system; Operation on the eyelids; Removal of biopsy or orbital tumors; Enucleation on eyeball; Exteneration of orbital contents.

Orthopedics: Cutting, ablation, and/or hemostasis of intra-articular tissue in Orthopedic surgical and arthroscopic applications.

Plastic Surgery: Cutting (incision/excision), coagulating, and vaporizing of soft tissue.

Pulmonary Surgery: Palliative treatment of benign and malignant pulmonary airway obstructions, including: Squamous Cell Carcinoma; Adenocarcinoma; Carcinoid; Benign Tumors; Granulomas; Benign Strictures.

Thoracic Surgery: Cutting (incision/excision), coagulating, and vaporizing of soft tissue. Thoracic applications including, but not limited to: Isolation of vessels for endarterectomy and/or by-pass grafts; Wedge Resections ; Thoractomy; Formation of Pacemaker pockets. Vaporization, coagulation,

K062719

incision/excision, debulking, and ablation of lung tissue (Thoracoscopy).

Urology: Urological Surgery (ablation, vaporization, incision, excision and coagulation of soft tissue) including: removal of superficial baldder tumors; removal of invasive bladder carcinoma; removal of benign or malignant lesions of the external genitalia including condylomas; treatment of urethral strictures; treatment of vascularitiesof the bladder wall; prostatectomy.

J. Rationale for Substantial Equivalence

Laserscope's GreenLight HPS™ Series Surgical Laser System & Accessories share the same indications for use, similar design features, functional features, and therefore are substantially equivalent to the: Laserscope's Lyra Surgical Laser System & Accessories, Lyra G™ Surgical Laser Systems & Accessories; the 800 Series Surgical Laser Systems and Accessories; the Modified Coherent VersaPulse Select Wavelength (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers and Delivery Devices and Accessories; and, the Laserscope Microbeam IV Micromanipulator. Details are provided in the Substantial Equivalence Section of this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 1 2006

Laserscope, LLC
% Mr. Paul H. Hardiman
Director, Regulatory Affairs
3070 Orchard Drive
San Jose, California 95134-2011

Re: K062719
Trade/Device Name: GreenLight HPS™ SURGICAL LASER SYSTEM & Accessories
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: November 6, 2006
Received: November 7, 2006

Dear Mr. Hardiman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K062719

Device Name: GreenLight HPS™ SURGICAL LASER SYSTEM & Accessories

Indications for Use:

The GreenLight HPS™ Surgical Laser System and Accessories are intended for the surgical incision/excision, vaporization, ablation and coagulation of soft tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands.

532nm Applications

General Surgery: Vaporizing, Coagulating, Incising, Excising, Debulking, and Ablating of Soft tissue as well as in Endoscopic (e.g. laparoscopic) or open surgeries.

Gastroenterology: Tissue ablation and hemostasis in the gastrointestinal tract; Esophageal neoplastic obstructions, including squamous cell carcinoma and adenocarcinoma; Gastrointestinal hemostasis (including Varices, Espohagitis, Esophageal Ulcer, Mallory-Weiss tear, Gastric Ulcer, Angiodysplasia, Stomal Ulcers, Non-bleeding Ulcers, Gastric erosions); Gastrointestinal Tissue ablation (Benign and Malignant neoplasm, Angiodysplasia, Polyps, Ulcer, Colitis, Hemorrhoids).

Gynecology: Vaporizing, incising, or coagulating tissue associated with treatments of conditions such as: Endometriosis; Cervical, vulvar, and vaginal intraepitheal neoplasia; Condyloma Acuminata; Uterine Septum; Intrauterine adhesions; Submucosal fibroids.

Head and Neck/Otorhinolaryngology (ENT): Tissue incision, excision, ablation, and vessel hemostasis.

Neurosurgery: Incising, excising, coagulating, and vaporizing neurological tumors of the firm textured type.

Opthamology: Post-vitrectomy endophotocoagulation of the retina.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X
(per 21 CFR 801.109)

or Over –The-Counter-Use

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K062719

510(k) Number: K062719

Device Name: GreenLight HPS™ SURGICAL LASER SYSTEM & Accessories

Plastic Surgery: Vaporizing, Coagulating, Incising, Excising, debulking, and ablating of soft tissue in endoscopic and open procedures.

Spinal Surgery: Percutaneous lumbar diskectomy.

Thoracic Surgery: Vaporizing, Coagulating, Incising, Excising, Debulking, and ablating of soft tissue, including lung tissue in thoroscopic or open procedures.

Urology: Cutting, coagulating, or vaporizing urologic soft tissues. Open endoscopic minimally invasive urological surgery (ablation, vaporization, incision, excision and coagulation of soft tissue) including treatment of: Bladder; Urethral & Ureteral Tumors; Condylomas; Lesions of external genitalia;Urethral & penile; Hemangioma; Urethral Strictures; Bladder Neck Obstructions; and, when used at 532nm it is intended to hemostatically vaporize prostate tissue of men suffering from benign prostate hyperplasia/hypoplasia (BPH). The device is not intended to treat prostate cancer.

1064 nm Applications

Endoscopic/Laparoscopic General Surgery: Cutting, ablation, and/or hemostasis of soft tissue in endoscopic or laparoscopic general surgery applications, including but not limited to: Cholecystectomy, Appendectomy, Vagotomy, Pyloromyotomy.
Soft tissue general surgery applications: Skin incision; Tissue dissection; Excision of external tumors and lesions; complete or partial resection of internal organs, tumors, lesions; Tissue ablation; Vessel Coagulation.

Gastroenterology: Tissue ablation and hemostasis in the gastrointestinal tract; Esophageal neoplastic obstructions including Squamous cell carcinoma and Adenocarcinoma;

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X or Over –The-Counter-Use

(per 21 CFR 801.109)

510(k) Number: K062719

Device Name: GreenLight HPS™ SURGICAL LASER SYSTEM & Accessories

Gastroenterology (contd.): Gastrointestinal hemostasis including: Varices, Espohagitis, Esophageal Ulcer, Mallory-Weiss tear, Gastric Ulcer, Angiodysplasia, Stomal ulcers, non-bleeding ulcers, Gastric erosions; Gastrointestinal tissue ablation including: Benign and malignant neoplasm; Angiodysplasia; Polyps; Ulcer; Colitis; Hemorrhoids.

Gynecology: Treatment of menorrhagia by photocoagulation of the endometrial lining of the uterus; Ablation of endometrial implants and/or peritoneal adhesions; Soft tissue excisional procedures, such as excisional conization of the cervix; intra-uterine gynecologic procedures where cutting, ablation and/or vessel coagulation may be indicated including Submucous fibroids, Benign endometrial polyps, Uterine septum.

Head and Neck/Otorhinolaryngology (ENT): Tissue incision, excision, ablation, and vessel hemostasis.

Hemostasis during Surgery: Adjunctive coagulation and hemostasis (bleeding control) during surgery in endoscopic (e.g. laparoscopic) and open procedures.

Neurosurgery: Hemostasis for: Pituitary Tumor; Meningioma; Hemagioblastoma; AVMs; Glioma; Glioblastoma; Astrocytoma; Oligodendroglioma.

Oculoplastics: Incision, Excision, Vaporization and/or coagulation of tissues in Oculoplastic procedures such as: Operations on the lacrimal system; Operation on the eyelids; Removal of biopsy or orbital tumors; Enucleation on eyeball; Exteneration of orbital contents.

Orthopedics: Cutting, ablation, and/or hemostasis of intra-articular tissue in Orthopedic surgical and arthroscopic applications.

Plastic Surgery: Cutting (incision/excision), coagulating, and vaporizing of soft tissue.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X or Over –The-Counter-Use

(per 21 CFR 801.109)

INDICATIONS FOR USE STATEMENT

510(k) Number: K062719

Device Name: GreenLight HPS™ SURGICAL LASER SYSTEM & Accessories

Pulmonary Surgery: Palliative treatment of benign and malignant pulmonary airway obstructions, including: Squamous Cell Carcinoma; Adenocarcinoma; Carcinoid; Benign Tumors; Granulomas; Benign Strictures.

Thoracic Surgery: Cutting (incision/excision), coagulating, and vaporizing of soft tissue. Thoracic applications including, but not limited to: Isolation of vessels for endarterectomy and/or by-pass grafts; Wedge Resections ; Thoractomy; Formation of Pacemaker pockets. Vaporization, coagulation, incision/excision, debulking, and ablation of lung tissue (Thoracoscopy).

Urology: : Urological Surgery (ablation, vaporization, incision, excision and coagulation of soft tissue) including: removal of superficial baldder tumors; removal of invasive bladder carcinoma; removal of benign or malignant lesions of the external genitalia including condylomas; treatment of urethral strictures; treatment of vascularities of the bladder wall; prostatectomy.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X or Over –The-Counter-Use

(per 21 CFR 801.109)